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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,670	07/23/2001	Andrew W. Taylor	ERI-114AX	6394

207 7590 09/15/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/912,670

Applicant(s)
Taylor et al.

Examiner
G.R. Ewoldt, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 10, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6 and 12-18, drawn to a method for generating T cells, classified in Class 435, subclasses 375 and 376.

II. Claims 7-11, 12-18, and 31-41, drawn to a method for downregulating an autoimmune response or other T cell mediated inflammatory response comprising exposing T cells to alpha-melanocyte stimulating hormone (α -MSH), classified in Class 424, subclass 278.1.

III. Claims 19-22 drawn to a kit, classified in Class 435, subclass 810, and Class 530, subclass 350.

IV. Claims 23, 25, and 28-30, drawn to a method for downregulating a graft rejection response or a T cell mediated autoimmune response comprising transfecting cells with genetic material for expressing α -MSH, classified in Class 514, subclass 44.

V. Claim 24, drawn to a method for downregulating a T cell mediated autoimmune response comprising injecting a tissue site with genetic material for expressing α -MSH, classified in Class 514, subclass 44.

VI. Claims 26 and 27, drawn to a method for suppressing a T cell mediated autoimmune response comprising injecting an animal with α -MSH, classified in Class 424, subclass 278.1.

The inventions are distinct, each from the other because:

2. Inventions I, II, and IV-VI are different methods. The Inventions comprise different reagents, different method steps and different endpoints. For example, methods of gene therapy, i.e., methods requiring the expression of exogenous genetic material, differ significantly from methods employing proteins. Therefore the methods are patentably distinct.

3. Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)).

In the instant case, the product as claimed can be used in materially different processes, such as for *in vitro* assays.

4. Because these inventions are distinct for the reasons given above and Groups I-VI have acquired a separate status in the art as shown by their different classification and/or the searches are not co-extensive, and because the Groups encompass divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
September 11, 2003